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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,403	09/12/2003	Andrew Vaillant	16051-4US CC	6672

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EXAMINER	
HURT, SHARON L	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/661,403	VAILLANT ET AL.	
	Examiner	Art Unit	
	Sharon Hurt	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *May 8, 2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Amendments to Claim 28, the Specification and new Claims 41-43, filed August 14, 2006 are acknowledged. Claims 1-27 and 30-40 are withdrawn. Claims 28-29 and 41-43 are pending and under examination.

Declaration

The declaration under 37 CFR 1.132 filed August 14, 2006 is sufficient to overcome the rejection of claims 28 and 29 based upon enablement.

Response to Arguments

Rejections Withdrawn

The objection of Claim 28 because it was dependant on non-elected or withdrawn claims is **withdrawn** pursuant applicant's amendments.

The rejection of Claim 28 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter of the claimed invention is **withdrawn** pursuant applicant's amendment.

Applicant's arguments, see pages 12-14, filed August 14, 2006, with respect to 35 U.S.C. § 112, first paragraph have been fully considered and are persuasive. The rejection of Claims 28 and 29 for failing to comply with written description has been **withdrawn**.

The rejection of Claims 28 and 29 under 35 U.S.C. § 112, first paragraph for enablement is **withdrawn** pursuant Declaration filed August 14, 2006 with evidence of experiments.

Rejections Maintained

The rejection of Claims 28-29 under 35 U.S.C. 102(b) as being anticipated by Andreola et al. (European Journal of Biochemistry, 2000, Vol. 267, pages 5032-5040) is maintained. The claimed invention of record. Andreola's teachings are of record.

Applicant argues that Andreola et al. (hereinafter Andreola) "teaches the identification of oligonucleotides having antiviral activity due to their sequence". Applicants further argue that Andreola teaches that some oligodeoxynucleotides are inhibitors of RNAse H activbity, while others are not, which applicant alleges demonstrates that Andreola et al. targeted specific sequences and that the activity is sequence dependent. Finally, applicant argues that Andreola et al. never realized that any sequence independednt oligonucleotide having at least one phophorothioate linkage had antiviral activity. Applicant's arguments filed August 14, 2006 have been fully considered but they are not persuasive for the following reasons.

Regarding the argument that Andreola only teaches that oligonucleotides have antiviral activity due to the sequence, applicant's attention is directed to page 267 of Andreola, wherein Andreola et al. teach that oligonucleotides "...folding into the pseudoknot motif were found to bind HIV-RT with high affinity (see column 2, first partial paragraph)". Andreola further teaches (at page 267), "The SELEX approach was also used to identify high affinity DNA ligands against HIV-1 RT...Although they showed little structural similarity to the RNA aptamers, they were able to bind the RT...and inhibited specifically the DNA polymerase activity..." (see column 2, second paragraph). While it is true that Andreola teaches selected sequences using the SELEX procedures, there is no teaching that the antiviral activity is limited

only to particular specified sequences. The teachings references *supra* would seem to indicate that the antiviral activity is not limited to specific sequences, but rather that a number of different oligonucleotides of different sequences have antiviral activity.

In response to the argument that Andreola teaches that some some oligodeoxynucleotides are inhibitors of RNAse H activity, while others are not, applicant is reminded that absolute predictability is not required, but rather a reasonable expectation of success. The teachings of Andreola support a reasonable expectation of success in inhibiting HIV-RT with oligonucleotides of differing sequences.

Finally, regarding applicant's argument that Andreola never realized that any sequence independent oligonucleotide having at least one phophorothioate linkage had antiviral activity, applicant is reminded that under the principles of inherency, if a prior art method, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art method. (MPEP 2112.02).

The rejection of Claims 28-29 under 35 U.S.C. 102(e) as being anticipated by Peyman et al. (US Patent No. 6,013,639) (hereinafter Peyman) is **maintained**. Peyman's teachings are of record. Applicant's arguments have been fully considered but they are not persuasive.

Applicant argues that claim 52 has been amended to define that the antiviral activity of the claimed oligonucleotides occurs principally by a non-sequence complementary mode of action. Applicant argues that Peyman "teaches that the efficacy of the tested oligonucleotides is dependent on the presence of a 10 guanines extension at each extremity of the oligonucleotide".

Applicant also argues that these oligonucleotides adopt a "G quartet" structure, which is not required in the present invention.

Firstly, regarding the 'G-quartet structure", applicant is arguing features which are not in the claims, as the absence of such a structure is not in the present claims. Furthermore, Peyman teaches administering the same oligonucleotides as those of the claimed invention (oligonucleotides at least 10 nucleotides in length) and teaches administering the oligonucleotides to the same patient population as the present invention (either normal subjects for prophylaxis against viral infection or patients with viral infection for treating the disease). Therefore, since Peyman teaches administering the same composition to the same patient population, the method of Peyman anticipates the claimed invention. The sequence independent mode of action is inherent to the oligonucleotide compositions of Peyman, which have antiviral activity. Furthermore, Peyman teaches that multiple oligonucleotides of distinct sequences all had antiviral activity. This is additional evidence that the oligonucleotides taught by inherently possess antiviral properties, which are independent of the specific sequence of the oligonucleotide.

The rejection of claims 28 and 29 on the ground of nonstatutory double patenting over claims 1-2 and 14-32 of copending Application No. 10/661,099, claims 1-38 of copending Application No. 10/661,088 and claims 1-2 and 14-32 of copending Application No. 10/661,415 are **maintained**. Applicant's statement of intention to file a terminal disclaimer upon indication of allowable subject matter is noted. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Hurt whose telephone number is 571-272-3334. The examiner can normally be reached on M-F 8:00 - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharon Hurt

December 6, 2006

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